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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,671	01/14/2002	Hendrik Johannis Boot	2183-5238US	9315
24247	7590	12/30/2005	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			PENG, BO	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,671

Applicant(s)

BOOT ET AL.

Examiner

Bo Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on September 23 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 11 and 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 10 and 12-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, filed on September 23, 2005. Applicant elects Group IV, claims 10 and 12-22, without traverse. Accordingly, claims 1-30 are pending. Claims 1-9, 11, and 23-30 are withdrawn from consideration as being directed to a nonelected invention. Claims 10, and 12-22 are examined in the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10, 14, and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The terms "incapable of" in claim 10 and "the incapacity" of claim 17 are relative terms which render the claims indefinite. The term "to substantially be propagated" of claim 17 is also indefinite. The terms of "incapable of" and "substantially" are not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree, which would allow one of ordinary skill in the art to be reasonably apprised of the scope of the invention.

5. Claim 10 remains vague and indefinite because the term “a nucleic acid comprising an IBDV genome at least partly derived from IBDV” does not define the metes and bounds of what specific part(s) of IBDV genome to be excluded or included from the claim language.
6. Claim 14 recites the limitation "one first cell" in claim 13. There is insufficient antecedent basis for this limitation in the claim. Regarding claim 14, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
7. Claim 18 recites the limitation "one permissive second cell" in claim 17. There is insufficient antecedent basis for this limitation in the claim.
8. Claim 19 recites the limitation "said rIBDV" in 18. There is insufficient antecedent basis for this limitation in the claim. Claim 19 recites, “said nucleic acid encodes at least a nucleic acid derived from at least a part of genome segment A of vvIBDV”. It is not clear which part of segment A is excluded or included from the claim language.
9. Claim 20 recites, “said nucleic acid encodes at least a functional part of protein VP2”. It is not clear what the function is and which part of VP2 protein is included in the claim.
10. Claim 21 is indefinite because it depends from narrower claims 20 and 19. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

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raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 21 recites the broad recitation of a nucleic acid derived from a serotype II IBDV, and the claim also recites claim 20. Claim 20 is directed to a V2 protein and is depend from “a part of genome segment A of vvIBDV” of claim 19, both protein V2 of claim 20 and vvIBDV of claim 19 are the narrower statements of the range/limitation than a serotype II IBDV of claim 21.

11. Appropriate corrections are required.

Claim Rejections - 35 USC § 112, first paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 10 and 12-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed*.” (See page

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1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detail chemical structure of the encompassed genus of undefined nucleotide fragment, proteins or polypeptides. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Applicant has disclosed a limited number of species; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a genus of protein sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

14. Claims 10 and 12-22 are drawn to a method for obtaining an infectious recombinant IBDV (rIBDV) incapable of growing on a non-bursa cell-derived cell. Since the limitation of rIBDV is incapable of growing on a non-bursa cell-derived cell, the scope of claim 10 encompasses all rIBDVs that are incapable of growing on a non-bursa cell-derived cell. It has been reported that some field isolates of serotype I IBDV stains (vvIBDV) fail to become adapted to cell culture *in vitro* (Mundt, 1999), although they can replicate in bursa lymphoid cells *in vivo*. Applicant discloses a few field isolates in the specification, however, Applicant has not disclosed sufficient species of rIBDVs to support the broadly claimed method for obtaining a

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genus of all IBDVs that are incapable of growing on a non-bursa derived cell. Consequently, while the skilled artisan would reasonably conclude Applicant was in possession of a method of obtaining a few field strains of rIBDV, there is no indication that Applicant was in possession of a method for obtaining all rIBDV that are incapable of growing in a non-bursa cell as broadly claimed.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 10, and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vakharia (5,871,744), Mundt (1999) and Muller (1982).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 10 and 12-22 are directed to a method for obtaining an infectious rIBDV, comprising transfecting one first cell with IBDV genome, propagating recovered rIBDV in one

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second cell which is permissive for said rIBDV, wherein the first cell is a CEF, a VERO or a QM5 cell, wherein the second cell is a primary bursa cell, wherein the rIBDV comprising a nucleic acid derived from a part of genome segment A of vvIBDV, wherein said nucleic acid encodes at least a part of IBDV VP2 protein.

18. Vakharia et al teaches a method of reverse genetics for generating rIBDV in cell culture system (claims 1-14 and throughout the text), since wild-type IBDVs usually do not replicate in conventional cell culture. Vakharia transfects VERO, CEF or CEK cells with both segments A and B of IBDV RNA, which resulting in the formation of infectious rIBDV progeny. Vakharia also teaches that a chimeric rIBDV could be generated when viral segment A and B are independently prepared from different strains of IBDV.

19. Vakharia does not teach further propagating rIBDV progeny in a second permissive cell.

20. Mundt teaches that the tissue culture infectivity (cell tropism) of different strains of IBDV is determined by their VP2 proteins. Mundt describes two types of strains of IBDV serotype I on the basis of their ability (IBDV-TC) or inability (IBDC-BU) to infect CEC cells in culture, although both types of IBDV can infect B lymphocytes in the bursa of Fabricius of young chickens (bursa-cell-driven). Mundt constructs a panel of chimeric rIBDVs by combining the segments of an IBDV-BU strain with segments encoding VP2 of an IBDV-TC strain and tested their ability to grow in CEC cells. Mundt also applies a method of propagating chimeric viruses using a two-cell system. For example, after having transfected QM7 cell with chimeric cRNA for two days, Mundt collects the supernatant of the QM7 cells containing the virus progeny, and propagated the virus progeny on CEC cells (p. 2072).

21. Mundt does not teach explicitly that propagate rIBDV in a primary bursa cell.

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22. Muller teaches that primary lymphoid cells from the bursa of Fabricicius, which are the nature host cell of IBDV serotype I strains, are more fit for IBDVs to grow in a cell culture *in vitro*. Muller observed that virus-specific protein altered while the virus was propagating in CEF cells, resulting in incomplete viral particles. By side-by-side comparison experiment using primary bursa cells and CEF cells, Muller shows that IBDV maintains its native viral particles while it was cultured in primary lymphoid cells from the bursa of Fabricicius.

23. One of ordinary skill in the art of avian virology is deemed to be aware of all the pertinent art in the field. The above references placed the knowledge of generating rIBDVs in vitro by reverse genetics, viral VP2 as a determinant factor of the cell tropism and propagation of an IBDV in vitro in the possession of artisan. The suggestion that growing IBDVs in their permissive cells or nature host cells can reduce unwanted incomplete viral particles, and be more fit for the virus to grow *in vitro* would motivate one skilled in the art to culture newly generated rIBDV progeny in primary permissive cells. One skilled in the art would also have re-directed the cell tropism of one strain of IBDV by incorporating a VP2 protein of another strain of IBDV with a desirable cell tropism because Mundt taught that VP2 protein is the determinate of the cell tropism. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Therefore, the invention as a whole was obvious over Vakharia, Mundt and Muller.

Remarks

24. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

BP


JEFFREY STUCKER
PRIMARY EXAMINER